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| 10/578,329 | 03/12/2007 | Olaf Stange | 2901652.4 | 5102 |

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Baker Donelson Bearman Caldwell & Berkowitz PC
920 Massachusetts Avenue
Suite 900
Washington, DC 20001

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| EXAMINER |
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SNYDER, STUART

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| ART UNIT | PAPER NUMBER |
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1648

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08/25/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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ltapp@bakerdonelson.com
smcbee@bakerdonelson.com

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| Office Action Summary | Application No. 10/578,329 | Applicant(s) STANGE ET AL. | |
| | Examiner STUART W. SNYDER | Art Unit 1648 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 June 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 7-12 and 14-20 is/are pending in the application.
- 4a) Of the above claim(s) 12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7-11 and 14-20 is/are rejected.
- 7) ☒ Claim(s) 10 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

1. Claims 1-5, 7-12 and 14-20 are pending; claim 12 is withdrawn from examination as being a non-elected invention. Amendment of the specification and claims 1, 11 and 14-19; and cancellation of claim 6 is acknowledged.

Claim Objections

2. Claim 10 is objected to because of the following informalities: Claim 10 recites, "pharmaceutical active ingredient". The phrase is idiomatic English and would properly read, "pharmaceutically active ingredient". Appropriate correction is required.

Claim Rejections - 35 USC § 112, ¶ 1

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-5, 7-11 and 14-20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for some aqueous solutions combined with some oils, does not reasonably provide enablement for any aqueous solutions combined with all oils. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. The claims are drawn to a method of making a water-in-oil-in-water emulsion (W/O/W) comprising the steps of dissolving an active ingredient into an aqueous

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phase by stirring, heating the aqueous phase and an oil phase to a temperature from 30° C to 35° C, emulsifying the aqueous and oil phases by mixing the two phases in a large-pored membrane and phase inversion of the heated emulsion by cooling the mixture at a cooling rate of at least 0.3 K/min, wherein an emulsifying agent is added to either or both of the aqueous and oil phases prior to emulsification.

It is well known in the emulsification arts that the temperature of emulsification is an important parameter in emulsification (see Joscelyne, et al.). The optimal temperature of emulsification depends on several parameters especially the viscosity of the various phases and the nature of the emulsifier as a consequence of phase inversion temperature. The emulsification temperature is dictated by the particular physical and/or chemical characteristics of the individual ingredients of the desired product. Only some of the wide variety of oils and only some of the wide variety of aqueous solutions will emulsify in the narrow temperature range. Applicant has provided only four examples with very similar constituents with which to illustrate the method claimed and hasn't demonstrated that other aqueous solutions with higher saline concentrations nor other oily phases would be able to produce stable emulsions by the claimed method. Thus, the specification does not enable the full scope of the claimed invention.

Claim Rejections - 35 USC § 112, ¶ 2

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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4. Rejection of claims 1-11 and 14-20 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is **withdrawn** in view of amendment of claims 1 and 11.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Rejection of claims 1-5, 7-10 and 14-17 under 35 U.S.C. 103(a) as being unpatentable over Higashi, et al., Joscelyne, et al., Moeritz, et al. and Forster, et al. is **maintained** for reasons of record and those below.

The claims are drawn to a method of preparation of a W/O/W emulsion comprising the steps of dissolving an active ingredient into an aqueous phase by stirring, heating the aqueous phase and an oil phase to a temperature from 30° C to 35° C, emulsifying the aqueous and oil phases by mixing the two phases in a large-pored membrane and phase inversion of the heated emulsion by cooling the mixture at a cooling rate of at least 0.3 K/min, wherein an emulsifying agent is added to either or both of the aqueous and oil phases prior to emulsification.

Further limitations are elaborated in the Office Action mailed 3/18/2010.

Applicants traverse the rejection for the following reasons: 1. The applied references do not teach or suggest step B, in particular, preheating the aqueous

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and oil phases to a temperature of 30-35° C; and 2. the applied references do not teach or suggest step C, in particular, a) phase inversion of the W/O emulsion into a W/O/W emulsion by cooling the W/O/ emulsion and b) there is no teaching or suggestion of the claimed cooling rate.

Applicants' arguments have been carefully considered and are not found to be persuasive. Regarding argument 1) no teaching of preheating of aqueous and oil phases to the recited temperature range: Joscelyne, et al. discloses that temperature can be an important parameter in emulsification affecting both the viscosity of the dispersed and continuous phases and also the nature of the emulsifier as a consequence of phase inversion temperature. [Section 3.5, in particular.] Joscelyne, et al. notes that emulsification temperature usually dictated by the requirements of a product. Because, temperature is explicitly taught to be a result-dependent variable, it is inherently obvious to optimize such a variable and, depending on the particular ingredients in the final emulsion product, a range of 30-35° C would be an obvious temperature range for preheating the water and oil phases.

Regarding Applicants' arguments phase inversion by cooling: Moeritz explicitly teaches heating and cooling a W/O emulsion to achieve phase inversion to achieve a W/O/W emulsion. The abstract of Moeritz does not specifically teach the cooling rate, however, as previously asserted, the cooling rate is a result-dependent variable (see, Encyclopedia of Pharmaceutical Technology, Vol. 3. James Swarbrick. Informa Healthcare USA, Inc. NY, NY. © 2007, p 1561).

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Because the cooling rate is a result-dependent variable, optimizing the cooling rate for the particular desired emulsion and arriving at a cooling rate of 0.3 or 1 K/min would be obvious to a skilled artisan.

Thus, the invention of claims 1-5, 7-10 and 14-17 is obvious over Higashi, et al., Joscelyne, et al., Moeritz, et al. and Forster, et al. and the claims are properly rejected under 35 U.S.C. 103(a).

6. Rejection of claims 1, 10-11 and 18-20 under 35 U.S.C. 103(a) as being unpatentable over Higashi, et al., Joscelyne, et al., Moeritz, et al., Forster, et al. and Ganne is **maintained** for reasons of record and those below. The limitation of the claims was described in the Office Action mailed 3/18/21010.

Applicants traverse the rejection for reasons applied to the rejection of claims 1-5, 7-10 and 14-17 over Higashi, et al., Joscelyne, et al., Moeritz, et al. and Forster, et al. and further argue that Ganne fails to cure the deficiencies of the combination of Higashi, et al., Joscelyne, et al., Moeritz, et al., and Forster, et al. However, that argument is rebutted above in section 5. Applicant further argues that there is no reason to combine the teachings of Higashi, et al., Joscelyne, et al., Moeritz, et al. and Forster, et al. with Ganne to arrive at a process to produce an emulsion comprising an active ingredient.

Applicants' arguments have been carefully considered and are not found to be persuasive. With regard to Applicants' contention that Higashi, et al., Joscelyne, et al., Moeritz, et al. and Forster, et al. fail to render obvious claims 1 and 10, Applicants are directed to section 5 above. With regard to the argument that

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there is no reason to combine the teachings of Higashi, et al., Joscelyne, et al., Moeritz, et al. and Forster, et al with that of Ganne: It is well known that emulsions are formed for various purposes such as cosmetics, food, pharmaceuticals, etc. Emulsions are one of several physical states to provide for such purposes and often produced because it is a particularly well-suited vehicle for the stated purposed. In the case of Ganne, the formulation of the active ingredients as an emulsion was because of the suitability of an emulsion format to facilitate delivery of the active ingredient. Ganne provides the motivation for using an emulsion as a vehicle to provide an active ingredient, "A first object of the invention is to provide therapeutic compositions comprising an adjuvant which allows an increase in the immune response which is at least equal to that imparted by aluminum hydroxide, without causing lesions or local reactions of the granuloma type and which is not liable to promote the appearance of diseases in the individual treated" (see Page 1, "Summary and Object of the Invention" section, 1st paragraph). Thus, it would have been obvious to include an active ingredient in a W/O/W emulsion and the process of making it and the claims are properly rejected under US 103(a) over the combination of Higashi, et al., Joscelyne, et al., Moeritz, et al., Forster, et al. and Ganne.

Conclusion

7. No claims are allowed.

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8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to STUART W. SNYDER whose telephone number is (571)272-9945. The examiner can normally be reached on 9:00 AM-5:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ZACHARIAH LUCAS can be reached on (571)272-0905. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mary E Mosher/
Primary Examiner, Art Unit 1648

Stuart W Snyder
Examiner
Art Unit 1648

SWS